REMARKS

Independent claims 1 and 16 have been amended to clarify the claimed subject matter. Claims 1-11 and 16-27 are pending.

In ¶ 4 of the Office Action, claims 1, 4, 5, 7, 11, 16, 19-21, and 24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fujimoto in view of Coolidge *et al.*, and further in view of Bayne. Applicant traverses this ground of rejection for the reasons set forth below and in the supporting Rule 132 declaration, which seeks to clarify the teachings of the Fujimoto, Coolidge and Bayne references. The Applicant respectfully requests that the statements made in the accompanying Rule 132 declaration be considered by the Examiner and given a weight worthy of pronouncements by a person skilled in the art.

At the outset, Applicant respectfully submits that the teaching of Coolidge is not fairly combinable with the teaching of Fujimoto. Consequently, it would not be obvious to combine the teaching of Coolidge with that of Fujimoto, as suggested by the Examiner. More specifically, Fujimoto teaches a home medical system that allows any patient or healthy person to measure his or her daily condition at home. A communication link connects the user's equipment at his home to a medical institution so that medical personal at the medical institution can review the measured results obtained by the user and make a diagnosis.

In contrast, Coolidge discloses methods for treating a patient suffering from acute coronary syndrome, but who is not suffering from a Q-wave myocardial infarction. Acute coronary syndrome (ACS) denotes patients who have or are at high risk of developing an acute myocardial infarction (MI). This complex includes unstable angina (UA), non-Q-wave cardiac necrosis (NQCN) and Q-wave MI. After ACS has been diagnosed, the patient is stratified into UA, NQCN or MI using various criteria. Coolidge discloses that the diagnostic criteria for UA and NQCN are quite different from those for Q-wave MI. For example, according to Coolidge, a Q-wave MI denotes a condition that is diagnosed in a patient who exhibits a pathological Q-wave, as indicated by ECG, and who has one or more of the following symptoms and signs: (1) ST elevation, as measured by ECG; (2) elevated blood levels of troponin I and troponin T, associated with a Q-wave MI; (3) elevated blood creatine kinase myocardial isoenzyme level, associated with a Q-wave MI; and (4) elevated blood lactate dehydrogenase level, associated with a Q-wave MI. The first criterion is based on the ECG acquired by the patient at his home; the second through fourth criteria require blood testing. A person skilled in the art would not expect the blood samples to be taken by the patient at his home and then shipped to the medical center. Nor does Coolidge disclose or suggest that the patient at home draws his own blood samples. The same is true for the diagnosis of UA and NQCN. Accordingly, one must conclude that the diagnostic criteria taught by Coolidge cannot be derived using the home

medical system of Fujimoto, which provides for the acquisition of an ECG at the home and does not provide or suggest the taking of blood samples in the home.

Accordingly, Applicant respectfully traverses the Examiner's assertion that it would be obvious to combine the teachings of Fujimoto and Coolidge "with the motivation of improving the treatment of ACS through early diagnosis and therapy with agents that prevent or reduce damage due to ACS." The home medical system of Fujimoto does not include blood testing, which the Coolidge diagnostic criteria require.

The Bayne patent discloses one embodiment in which the patient at his home initiates a call to a call center and another embodiment where an Internet-capable medical device 106 (see Bayne, Fig. 1) automatically requests that the call center send a clinician to the patient's home, e.g., in response to detection of a medical condition such as dangerously low blood pressure (see Bayne, ¶ 0078). Neither embodiment contemplates blood testing at the patient's home. Accordingly, Coolidge is not combinable with Bayne for the same reason.

Furthermore, Figure 6 of Fujimoto shows the steps of a procedure for measurement of an electrocardiogram. In accordance with the Fujimoto teaching, the user puts two measuring electrodes 18 (see Figures 2 and 4 of Fujimoto) on his/her arms (see col. 5, lines 36-38). However, as explained in the Rule 132 declaration submitted herewith, acute coronary syndrome (ACS) cannot be detected via a pair of measuring

electrodes.

In contrast, amended claims 1 and 16 recite the acquisition of 12-lead electrocardiograms. This claim limitation is fully supported by the specification. For example, the paragraph at lines 28-35 on page 10 states that the preferred embodiment of the invention uses applications software that comprises "the previously described 12SL® program. As previously described on page 2, lines 8-10, the 12SL® program "is a computer program for analyzing simultaneously acquired 12-lead ECGs". More than a pair of electrodes is necessary for measuring the contour of the waves. An analysis of the contour is necessary for the recognition of ACS. Accordingly, it would not have been obvious to a person skilled in the art to use the home medical system of Fujimoto to detect ACS.

U.S. Patent Appln. Publ. No. 2005/0060198 to Bayne discloses a system having the object of enabling people "to receive acute care in their home or workplace" (see Bayne, ¶ 0007). This is completely different than applicant's claimed invention in which acute care, namely, surgery involving the insertion of a catheter, is provided in a catheterization lab. All of the advantages of the Bayne system (set forth in ¶ 0013 of Bayne) derive from provision of medical care at a remote location away from a central medical facility. Thus the idea of examining patients and then scheduling surgery for ACD at a catherization lab, as disclosed in the instant application, is

completely different and even opposite to the teaching of Bayne.

Furthermore, as set forth in detail in the Rule 132 declaration submitted herewith, in accordance with the teaching of Bayne, a triage processing block 114 at the call center 110 determines whether the patient's situation constitutes a life-threatening emergency. However, this criticality determination must be made without the benefit of blood testing or 12-lead ECGs. In other words, according to the teaching of Bayne, prior to the dispatch of a clinician to the patient's home or workplace, there is insufficient information from the patient to diagnose acute coronary disease.

In addition, Bayne does not disclose or suggest expert system software that operates on ECG data for determining whether the patient has a high probability of acute coronary syndrome. Instead, the expert system software, mentioned in ¶ 0073 of Bayne, is part of the triage processing block, which operates based only on the limited information provided by the patient or by the aforementioned remotely located home medical device 106, i.e., based on information that does not include 12-lead ECG data. Thus, one cannot infer that the expert system software of Bayne is capable of determining that the remotely located patient has acute coronary syndrome because the information necessary to such determination is clearly absent. Moreover, it must be noted that the words "acute coronary syndrome" and "catheterization"

appear nowhere in Bayne.

As further explained in the Rule 132 declaration, the triage processing block 114 responds to a call for medical assistance by determining whether emergency services or a medical care clinician should be sent to the patient. In the former case, the triage processing block 114 directs the web server 113 to display a message instructing the patient to obtain emergency ambulance services, for example, by dialing "911". [Bayne, ¶ 0071.] In other words, the patient must fend for him/herself and the triage processing block takes no steps to provide emergency medical treatment. ¶ 0073 of Bayne discloses that the triage processing block "determines the appropriate clinician type and equipment required to treat the patient's reported condition." However, as seen in Figure 4 of Bayne, this occurs only if a determination has been made during triage that there is no emergency. Obviously, acute coronary syndrome is an emergency, in which case the triage processing block would never get to step 418 of determining the required clinician type. In an emergency, no clinician is sent to the patient's home. Therefore the Bayne system does not envision calling a cardiologist to go to the patient's home if the patient is suffering from acute coronary syndrome.

Thus, Bayne teaches away from providing a computer that will analyze ECG data to determine whether the patient is suffering from acute coronary syndrome. Nor does Bayne teach anything about automated scheduling. The Examiner cites ¶ 0098

of Bayne for the proposition that the clinician can utilize the clinician device to complete an on-line hospital admission process. Purportedly, this would take the form of the clinician providing a predetermined message and "the clinician device - i.e., a computer - scheduling the procedure" (page 5 of action). This rationale is flawed. In the first place, admission to a hospital is not the same thing as scheduling "an emergency procedure". The term "scheduling" implies the setting of a time and place for the emergency procedure. For example, the verb "schedule" is defined as follows in Webster's II New College Dictionary: "to plan or appoint for a certain date or time." Sending an ambulance in response to an emergency is done as soon as possible without "scheduling". Bayne neither discloses nor suggests scheduling of an emergency procedure.

In summary, a person skilled in the art would not view the home care systems of Fujimoto and Bayne as suggesting providing emergency treatment for ACD in a hospital setting.

In view of the foregoing, the Applicant submits that independent claims 1 and 16 and claims 4, 5, 7, 11, 19-21, and 24 dependent thereon are not obvious in view of the combination of Fujimoto, Coolidge and Bayne.

In ¶ 5 of the Office Action, claims 2, 3, 6, 8-10, 17, 18, 22, and 25-27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Fujimoto in view of Coolidge and Bayne as applied to claim 1, and further in view of Admitted

Prior Art. The Applicant traverses this ground of rejection for the same reasons set forth above and for the following further reasons.

Vis-à-vis the rejections of claims 2 and 3, Bayne teaches automated scheduling of a clinician's visit to a patient's home. The mere existence of an emergency coronary treatment facility where PTCA is performed does not make it obvious to schedule such a procedure at such a facility in response to electrocardiogram data analysis results indicating an acute cardiac condition. As previously noted, the system taught by Bayne is designed to send out clinician's to patients' homes to provide non-emergency medical treatment.

Vis-à-vis claim 6, the Examiner's assertion that the pre-scheduled appointment block of Bayne "could be programmed to access the schedules of the treatment facilities" is irrelevant to an obviousness inquiry. The mere possibility of doing something does not establish a *prima facie* case for obviousness. The Applicant also disagrees with the assertion that "communication with local hospital admissions resources would provide access to schedules for the treatment facilities within the hospitals." This statement has no basis in fact and is unsupported by citation to prior art. Moreover, the "treatment facilities" recited in claim 6 would obviously be located at different hospitals and thus would not be accessible from the admissions office of a single hospital.

Accordingly, the Applicant requests that the obviousness rejection of claims 2, 3, 6, 8-10, 17, 18, 22, and 25-27 also be withdrawn.

In view of the foregoing, the Applicant submits that this application is now in condition for allowance. Reconsideration of the application and allowance of claims 1-11 and 16-27 are hereby requested.

Respectfully submitted,

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Date

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March 1, 2007
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